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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,521	GIRTON ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,11-16 and 21-24* is/are pending in the application.

4a) Of the above claim(s) *4 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

The applicant's have questioned the rejections made in the office action mailed September 9, 2004, specifically wondering why the references (Pinchuk and Zilla) were applied, when they were previously overcome. The examiner's response is as so: applicants claims are product by process claims. The applicant's previous claims seemed to focus in on the intermediate product, and the applicant's current claims focus more on the end product, which has a different structure than the intermediate product and thus the claims are interpreted different by the examiner. Also, in the interview summary, the examiner stated the proposed amendments seemingly overcame the previous rejection, however would require further consideration, and it is further noted, that the examiner is not bound to any certain grounds due to the discussions in an interview. In addition, an RCE was filed, with amendments to the claims, and a new examination, interpretation, and analysis is permitted and required by the examiner. And upon further review of the amended claims, it is the examiner position that Pinchuk and Zilla are readable on the current claims.

Applicant's arguments filed December 9, 2004 have been fully considered but they are not persuasive. The applicant has argued that both Pinchuk (US 4,657,544) and Zilla (US 6,540,780) do not disclose interpenetrating polymer networks (IPN's). The examiner's response is as follows: The applicant's claims are product by process claims, see MPEP 2113. The applicant's end product or "medical device" or "vascular graft" as implanted, is not an IPN (because the extracted polymer is **not** present). The IPN is an intermediate product, and is not present in the end product, and therefore, an IPN is not required in the references. The same

goes for the extracted polymer. There is **no** "extracted polymer" in the end product, and an extracted polymer is **not** required by the references. Therefore, the end product, as claimed by the applicant only requires a non-expanded tube of PTFE with pores. The only structure required by the references is non-expanded PTFE with pores, the pores having a shape of previously present polymeric material. Pinchuk and Zilla both discloses a tubular medical device comprising non-expanded PTFE and pores, the pores both having a size and shape like the size and shape of applicant's pores made by extracting a polymer. The rejections stand.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk (US 4,657,544, cited by applicant in IDS). Reciting the claims, referring to claims 1 and 3, Pinchuk discloses a medical device/vascular graft (10; col.1, lines 6-11) comprising an implantable tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising an interpenetrating polymer network (the IPN is not present in the end product and therefore, not required to be present in Pinchuk; however it is noted that Pinchuk does disclose an IPN according to applicant's supplied definition, Pinchuk discloses PTFE and polyurethane, and silicone, together, and which are crosslinked together, as required to be an IPN by applicant supplied definition in arguments filed December 9, 2004; therefore, whether Pinchuk does or does not discloses an IPN is irrelevant, since it is not present in the applicants end product and

thus not required by the claim) comprising a non-expanded PTFE matrix having no node and fibril structure (graft 10 comprises PTFE, polytetrafluoroethylene, col.4, lines 4-10), the matrix having distributed therein discrete domains of an extractable polymeric material (polymeric material is not required by Pinchuk, since it is not present in the end product; however, Pinchuk's salt crystals act as the polymeric material, that is perform the function of creating pores; the salt is not polymeric, however need not be, since they are eventually extracted, and are not present in the end product and thus not required in the claim), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material (salt) is extracted from the matrix to create pores (16) in the tubular extrudate ("Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir.1985), extraction of polymeric material is a product by process limitations, the end product is a PTFE porous extrudate; Pinchuk discloses extracting salt to create pores, leaving a porous PTFE extrudate, the same end product, col.4, lines 48-52; because the applicants polymeric material is extracted, whether it was polymeric or not, does not matter, since it is not present in the end product. The salt that is extracted in Pinchuk, forms the same end product as extracting polymeric materials would, a porous structure comprising PTFE, see MPEP 2113) which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Referring to claim 21, as recited, Pinchuk discloses an extractable polymeric material to comprise silicone (this is a product-by-process limitation, the silicone is claimed to be extracted, therefore not present in the end product and Pinchuk's does not disclose polymeric material, and further is not required to, since the salt crystals act as the polymer and create the same porous end product).

Referring to claim 22, as recited, Pinchuk discloses a medical device (10) comprising a tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising an interpenetrating network (the IPN is not present in the end product and therefore, not required to be present in Pinchuk; however it is noted that Pinchuk does disclose an IPN according to applicant's supplied definition, Pinchuk discloses PTFE and polyurethane, and silicone, together, and which are crosslinked together, as required to be an IPN by applicant supplied definition in arguments filed December 9, 2004; therefore, whether Pinchuk does or does not discloses an IPN is irrelevant, since it is not present in the applicants end product and thus not required by the claim) comprising a non-expanded PTFE matrix having no node and fibril structure (graft 10 comprises PTFE, polytetrafluorethylene, col.4, lines 4-10), the matrix having distributed therein discrete domains of an extractable polymeric material (polymeric material is not required by Pinchuk, since it is not present in applicant's end product; however, Pinchuk's salt crystals act as the polymeric material, that is perform the function of creating pores; the salt is not polymeric, however need not be, since they are eventually extracted, and are not present in the end product and thus not required in the claim), the extractable polymeric material being particulate having a particle size of about 5-100 microns (col.3, lines 38-42; col.6, lines 14-17), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric

material is extracted from the matrix to create pores (16) corresponding to the particle size in the tubular extrudate ("Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir.1985), extraction of polymeric material is a product by process limitations, the end product is a PTFE porous extrudate; Pinchuk discloses extracting salt to create pores, leaving a porous PTFE extrudate, the same end product, col.4, lines 48-52; because the applicants polymeric material is extracted, whether it was polymeric or not, does not matter, since it is not present in the end product. The salt that is extracted in Pinchuk, forms the same end product as extracting polymeric materials would, a porous structure comprising PTFE, see MPEP 2113) which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Referring to claim 23, as recited, Pinchuk discloses an implantable, non-expanded, porous PTFE extrudate (10) comprising a tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising non-expanded PTFE having no node and fibril structure (graft 10 comprises PTFE, polytetrafluorethylene, col.4, lines 4-10) and a plurality of pores (16) distributed throughout the non-expanded PTFE (fig.1), the pores (16) having a shape defined by an extracted polymeric material (shape shown in fig.2), the polymeric material being in a form selected from the group consisting of a gel, liquid and flowable material (this is a product-by-process limitation, see above; the salt crystals of Pinchuk may have the shape of liquid droplets or gel

droplets or clumps, therefore, the same end product results, whether the beginning product has liquid, gels, or salt).

Referring to claim 24, as recited, Pinchuk discloses an implantable PTFE extrudate (10) comprising a non-expanded PTFE resin having no node and fibril structure (col.4, lines 4-9), and a particulate polymeric component (salt, although not a polymer, a polymer is **not** required, since this is a product-by-process limitation and the polymeric component is extracted and not present in the end product upon implantation) which is incompatible with the non-expanded PTFE resin, wherein discrete domains of the polymeric component are distributed through out the non-expanded PTFE resin and are extractable therefrom to create pores (16) in the PTFE resin which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk (US 4,657,544, cited by applicant in IDS) in view of Dereume et al. (UPSN 5,639,278, cited in previous office action). Pinchuk discloses a medical device (vascular graft, 10) comprising a tubular extrudate (col.4, lines 45-49), which comprises a non-expanded porous (16) PTFE matrix (col.4, lines 4-10). Pinchuk does not teach however, a stent combined with the graft. Dereume teaches in the same field of medical devices, combining an axially positioned stent (22) within a graft (23 or 24), in order to provide increased support on the graft to better hold open the vessel

(col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent with a graft, with Pinchuk's specific type of graft, in order to provide a medical device that more properly supports an artery or a vein.

Claims 1, 3, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilla et al. (US 6,540,780 B1, cited in previous office action). Referring to all claims, (and also, see arguments above) Zilla discloses an implantable medical device/vascular graft (col.1, lines 11-16) comprising a polymeric tubular extrudate (18, 30; col.4, lines20-28; col.7, lines 46-55; col.3, lines 19-22) having distributed therein discrete domains of an extractable polymeric material (14, 36; particles, liquids, and gels all are disclosed by Zilla as extractable materials, fibers, fillers; col.3, lines 45-58; col.4, lines 55-67; col.6, lines 9-16, 61-63), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material is extracted from the extrudate matrix to create pores (col.3, lines 46-57; col.4, lines 55-67; col.8, lines 62-67) which upon implantation permit tissue ingrowth. Zilla discloses a medical device/vascular graft substantially as claimed, however discloses use of polymers such as polyurethane for the extrudate instead of non-expanded unfibrillated PTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an extrudate of PTFE (a commonly used material for vascular grafts) instead of polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER